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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,899	10/12/2001	Douglas J. Goetz	D6379	1164

7590            04/08/2003

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[REDACTED]  
EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/975,899	GOETZ ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Michail A Belyavskyi	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 21 January 2002.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 6-7 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____                                     |

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 1/21/02 (Paper No. 8 ), is acknowledged.

Claims 1-7 are pending.

Claims 1-5 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

*Claims 6-7 drawn to a method of treating cancer, comprising administering biodegradable particles that binds to ICAM-1 or P-selectin, wherein targeting molecule include antibody or antibody fragments that bind ICAM-1 or P-selectin are under consideration in the instant application.*

In view of the amendment, filed 1/21/02 (Paper No. 8 ), only the following rejections remain:

2. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

3. Claims 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is improper to recite "wherein said pathophysiological state is selected from the group consisting of cancer" because there is no other pathophysiological state recited in claim 7 . It is suggested that said phrase be change to "wherein said pathophysiological state is cancer " for clarity and consistency .

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 6 and 7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hallahan (US Patent NO: 6,159,443) in view of the know fact disclosed in the specification on pages 4, lines 15-20 ; 5, lines 1-5; and 10, lines 12-20 and Mastrobattista et al.,(Biochim. Biophys. Acta, 1999, 1419, 353-363) essentially for the same reasons set forth in the previous Office Action, Paper No: 7, mailed 10/22/02

Applicant's arguments, filed 1/21/02 (Paper No. 8 ), have been fully considered, but have not been found convincing.

Applicant asserts that: (i) the method taught by Hallahan is different from the method of present claims because Hallahan does not explicitly teach that delivery vehicles is biodegradable particle comprising antibody that bind to P-selectin or ICAM-1 ; and (ii) Mastrobattista et al, thought teach biodegradable particle comprising antibody that bind to ICAM-1, does not teach the use of irradiation to increase the expression of the cell adhesion molecules in the cell.

Applicants have traversed the primary and the secondary references pointing to the differences between the claims and the disclosure in each reference. Applicant is respectfully reminded that the rejection is under 35 USC103 and that unobviousness cannot be established by attacking the references individually when the rejection is based on the combination of the references. see In re Keller, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981) See MPEP 2145. This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. In re Young 403 F.2d 759, 150 USPQ 725 (CCPA 1968).

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Hallahan et al., teach a method of treating cancer , the method comprising steps of exposing a target tissue or organ to the ionizing radiation and administering a delivery vehicle (see entire document, Abstract and column 13, lines 24-30 in particular). Hallahan et al., teach that delivery vehicle is a biodegradable particles bearing molecules that bind to a cellular adhesion molecule expressed on endothelial cells ( column 7-8 in particular). Hallahan et al., also teach that said molecules are antibody or antibody fragments that specific for P-selectin (column 8, lines 17-21 in particular). Hallahan et al., also teach that there is a substantial need for an improved method for a selective delivery of therapeutic or imaging agents using biomolecular carrier bearing antibodies to cellular adhesion molecule that overexpressed on endothelial cells (column 2, lines 36-45 in particular) after irradiation.

The known fact disclosed in the specification on pages 4, lines 15-20 ; 5, lines 1-5; and 10, lines 12-20 teaches that exposure of diseased tissue to irradiation causes an increase expression of several cellular adhesion molecule on endothelial cells, including P-selectin and ICAM-1.

Mastrobattista et al. teach biomolecular carrier, bearing anti ICAM-1 antibodies (see entire document, Abstract in particular). Mastrobattista et al. also teach that biomolecular carrier, bearing anti ICAM-1 antibodies can be effectively used to delivery drugs to the sites where the expression of ICAM-1 is increase.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Mastrobattista et al. and known fact disclosed in Specification on pages 4, lines 15-20 ; 5, lines 1-5; and 10, lines 12-20 to those of Hallahan et al. and substitute biomolecular carrier bearing antibodies to one cellular adhesion molecule(P-selectin) to biomolecular carrier bearing antibodies to another cellular adhesion molecule (ICAM-1), since the expression of any one of them would be enhanced in target tissue after irradiation, to obtain a claimed method of treating cancer, comprising the steps of irradiating a target tissue or organ and administering the biomolecular carrier bearing antibodies that specific to ICAM-1.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because Mastrobattista et al. teach that biomolecular carrier, bearing anti ICAM-1 antibodies can be effectively used to delivery drugs to the sites where the expression of ICAM-1 is increase and known fact disclosed in Specification on pages. teaches that in response to irradiation there is an enhanced expression of several cellular adhesion molecule on endothelial cells, including P-selectin and ICAM-1 and Hallahan et al., teach that there is a substantial need for an improved method for a selective delivery of therapeutic or imaging agents using biomolecular carrier bearing antibodies to cellular adhesion molecule that overexpressed on endothelial cells.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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April 7, 2003

  
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